If we review the history of those, you will find that it was pointed out that the Food and Drug Administration from the very first had been reaching safety decisions on balancing benefit to risk. Else there could not have been the drugs on the market we have today.

Senator McINTYRE. It is my understanding that in your answer you are not talking about the legislative history of the enactment of the 1938 law, but about the hearings and discussions before the Intergovernmental Relations Subcommittee of the House.

Mr. GOODRICH. Intergovernmental Relations Subcommittee of the House Committee on Government Operations was one group. Senator Humphrey had a drug investigation here in the Senate, so did Senator Kefauver. This issue has been a recurring one at every discussion of the activities of the Food and Drug Administration in this area. I am simply trying to summarize it briefly, to say that any drug that has any benefit at all is very likely to have side effects and contraindications.

A medical judgment has to be made on that basis. We did elucidate our thinking in this in more detail before the Fountain Subcommittee than any other place I know of.

Senator McINTYRE. Well, actually, as I understand it, what you have given us here is a summary of what FDA's interpretation has been as explained to various committees in the Congress.

Mr. GOODRICH. Yes.

Senator McINTYRE. Wouldn't it have been better to have said that, instead of talking about the intent of the legislation? Wouldn't this be more accurate?

Mr. GOODRICH. Probably so, I did not write the sentence, and I might not have chosen those words. But I do accept full responsibility for having talked with Dr. Hellman about this and having directed him to that discussion of the benefit-to-risk issue that was elucidated before the Fountain Subcommittee. That was the place that I knew that it had been explained in most detail.

I sent him a photocopy or Xeroxed copy of that discussion.

Senator McINTYRE. I understand what this is now. Actually, in 1938, the law was just absent of any legislative history explaining the intent with respect to the statutory meaning of the word "safe".

Mr. GOODRICH. And the reason was that the revision of the Federal Food and Drug Cosmetic Act started in 1933. It was practically at the end point in 1937. The bill, indeed, had passed both Houses of Congress, when the elixir sulfanilamide episode occurred. This focused on the need for new drug provisions.

These provision were proposed as separate legislation and were added on to that legislation at the very end, and there was no real discussion of the legislative intent there, other than to be sure that we protected the public from episodes of acute poisoning, which was what had been involved in the elixir sulfanilamide case.

Senator McINTYRE. Thank you.

On page 6, Mr. Commissioner, you state that FDA met with industry representatives on November 14, 1969, to discuss labeling changes pursuant to the second part of the Hellman Committee report.